DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 24, 2014

Depuy Mitek, A Johnson & Johnson Company
Ms. Tracey Hannon
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142574
Trade/Device Name: Healix Ti with Permacord
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 25, 2014
Received: September 26, 2014

Dear Ms. Hannon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142574

Device Name
Healix Ti with Permacord

Indications for Use *(Describe)*

The Healix Ti Anchor is intended for:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Patellar Tendon repair and secondary fixation in ACL/PCL reconstruction repair

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hip: Capsular Repair, Acetabular Labral Repair

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 2 - 510(k) SUMMARY

Healix™ Ti Anchor with Permacord™

Submitter's Name and Address

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Date Prepared: September 11, 2014

Contact Person

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Name of Medical Device

Proprietary Name: Healix Ti™ Anchor with Permacord™

Classification Name: Smooth or threaded metallic bone fixation fasteners

Common Name: Suture Anchor

Substantial Equivalence

The Healix Ti™ Anchor with Permacord™ is substantially equivalent to:
- K082282 Healix Ti™ Anchor with Orthocord®

Reference Devices:
- K133794 Healix Advance™ Anchor with Permacord™
- K140324 Rigidloop™ Adjustable Cortical Fixation System

Device Classification

- Healix Ti™ Anchor with Permacord™ is classified as:
  - Smooth or threaded metallic bone fixation fastener, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.

Device Description

The Healix Ti™ Anchor with Permacord™ is a non-absorbable suture anchor preloaded on a disposable inserter assembly intended for fixation of suture to bone. The Healix Ti Anchors are manufactured of Titanium material. Permacord suture is non-absorbable. The anchor is provided in three sizes: 4.5mm, 5.5mm and 6.5mm. The Healix Ti Anchor with Permacord suture is supplied sterile and is for single use only.

Technological Characteristics

The proposed Healix Ti anchor with Permacord suture has the same anchor materials and design as the predicate Healix Ti anchor with Orthocord (K082282). The proposed device principal operation is the same as predicate Healix Ti anchor

	(K082282). The Permacord suture is the same suture as referenced in Healix Advance™ Anchor with Permacord™ (K133794).
Indications for Use	The **Healix Ti Anchor** is intended for: **Shoulder**: Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction; **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Patella tendon repair and secondary fixation in ACL / PCL reconstruction repair. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction. **Hip**: Capsular repair, acetabular labral repair.
Non clinical Testing	Verification activities were performed on the implant and / or its predicates. Testing assessment includes pull out testing.
Safety and Performance	Results of performance testing have demonstrated that the proposed device is suitable for its intended use. Based on similarities in the indications for use, technological characteristics, and performance in comparison to the predicate device, the proposed Healix Ti Anchor with Permacord suture has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.
Conclusion	The proposed Healix Ti Anchor with Permacord suture is substantially equivalent to Healix Ti Anchor with Orthocord suture (K082282) in terms of design, indications for use, performance data, sterilization method and shelf life.